DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Heather Crawford, RAC
Director of Regulatory Affairs
Vanguard Medical Concepts, Inc
5307 Great Oak Drive
LAKELAND FL 33815

Re: K011800 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: NLU
Dated: September 7, 2001
Received: September 10, 2001

Dear Ms. Crawford:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on September 10, 2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

The following list is the models used in this submission.

K011800: Vanguard Reprocessed Electric Biopsy Forceps
Microvasive® Radial Jaw® 3, Model 1550
Bard Precisor, Model 852
Bard Precisor, Model 853
Bard Precisor, Model 854
Bard Precisor, Model 856

K011800

Indications for Use

510(k) Number: K011800

Device Name: Vanguard Reprocessed Electric Biopsy Forceps

Indications for Use:

When used with a compatible electrosurgical unit, endoscope and patient grounding pad, electric biopsy forceps are intended for electrocautery and removal of polyps and/or tissue within the gastrointestinal tract. The forceps are prescription devices intended for a single patient use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011800

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K011800
Page 1 of 2

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

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(863) 683-8680, extension 228
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Date

May 31, 2001

Devices

- Trade Names: Vanguard Reprocessed Electric Biopsy Forceps
  ⇒ Boston Scientific Microvasive® Radial Jaw® 3, and
  ⇒ C.R. Bard Precisor® Electric Biopsy Forceps
- Common Name: Electric biopsy forceps
- Classification: 21 CFR 876.4300 – Endoscopic Electrosurgical Unit and Accessories – Class II
- Product Code KGE

Predicate Devices

- Boston Scientific Microvasive® Radial Jaw® 3 Electric Biopsy Forceps believed to be legally marketed under 510(k) premarket notification K860366
- C.R. Bard Precisor® Hot Biopsy Forceps believed to be legally marketed under 510(k) premarket notification K912601

Indications for Use

When used with a compatible electrosurgical unit, endoscope and patient grounding pad, electric biopsy forceps are intended for electrocautery and removal of polyps and/or tissue within the gastrointestinal tract. The forceps are prescription devices intended for a single patient use only.

Continued on next page

Microvasive and Radial Jaw are registered trademarks of Boston Scientific Corporation
Precisor is a trademark of C.R. Bard, Inc.

510(k) Summary of Safety & Effectiveness, Continued

Device Description

Biopsy forceps are devices used to collect tissue samples and/or remove polyps within the gastrointestinal tract via the operating channel of endoscopic instruments.

Electric biopsy forceps include an electrocautery function when used with a compatible electrosurgical unit.

The devices consist of flexible, electrically isolated sheaths with distal grasping cups that are controlled by a proximal handle. The forceps are guided by endoscopy through a biopsy channel with a minimum dimension of 2.8 mm. Monopolar electrocautery requires electrical connection of the forceps to a compatible electrosurgical unit and use of an appropriate patient grounding pad.

Vanguard receives previously used electric biopsy forceps from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the forceps; and returns them to the healthcare facility.

Technological Characteristics

The technological characteristics of the Vanguard reprocessed electric biopsy forceps are the same as the predicate devices, the original equipment manufacturer (OEM) electric biopsy forceps. The materials and dimensions are unchanged and the physical characteristics, performance specifications, and all other characteristics are essentially identical.

Test Data

Decontamination and cleaning, packaging and sterilization validations and functional/performance, shelf life and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed electric biopsy forceps are substantially equivalent to the predicate device, the respective OEM biopsy forceps under the Federal Food, Drug and Cosmetic Act.